

Clinical Trial Protocol

Iranian Registry of Clinical Trials

02 Jun 2026

Evaluation of the effect of high-dose vitamin C in the treatment of patients with COVID-19 admitted to the critical care ward

Protocol summary

Study aim

The aim of this study was to evaluate the effect of high dose intravenous vitamin C in COVID-19 patients admitted to the intensive care unit.

Design

Clinical trial with control group, with parallel, non-blind, randomized, phase 2 groups on 200 patients. Excel software rand function will be used for randomization.

Settings and conduct

Patients are randomly divided into intervention and control groups according to the treatment protocol of the Ministry of Health and in the intervention group, despite treatment with standard protocol, vitamin C is also prescribed. This treatment will be every 12 hours and 4 grams per day.

Participants/Inclusion and exclusion criteria

Inclusion criteria: adults (18 years and older); respiratory failure index (RIF) (arterial oxygen stress (or pressure)/ fraction-inspired oxygen) <300 mm Hg; treated in ICU. Exclusion criteria: patients with a history of vitamin C allergy; patients with asthma due to cardiopulmonary edema; pregnant or lactating women; patients whose survival time is less than 24 hours; patients with a previous history of end-stage lung disease, end-stage malignant tumor, G-6-PD deficiency, diabetic ketoacidosis, active kidney stone disease, and severe kidney disease; patients who have already enrolled in another clinical trial; patients with a known history of kidney disease, chronic renal failure, or acute renal failure during hospitalization will be excluded from the study.

Intervention groups

Intervention group: COVID-19 patients will receive standard drugs of the national protocol and vitamin C by injection. The control group includes patients who receive standard drugs of the national protocol and vitamin C placebo.

Main outcome variables

Oxygen saturation; respiration rate; length of hospital

stay; mortality rate

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20210714051891N1**

Registration date: **2021-09-29, 1400/07/07**

Registration timing: **prospective**

Last update: **2021-09-29, 1400/07/07**

Update count: **0**

Registration date

2021-09-29, 1400/07/07

Registrant information

Name

Moloud Balafar

Name of organization / entity

Country

Iran (Islamic Republic of)

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+98 41 3335 2078

Email address

balafarm@tbzmed.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-10-07, 1400/07/15

Expected recruitment end date

2021-12-06, 1400/09/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of the effect of high-dose vitamin C in the treatment of patients with COVID-19 admitted to the critical care ward

Public title

The effect of vitamin C in the treatment of patients with COVID-19

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Respiratory failure index (RIF) Treated in the ICU

Exclusion criteria:

Patients with a history of vitamin C allergy. Patients with asthma due to cardiopulmonary edema Pregnant or lactating women Patients with a survival time of less than 24 hours Patients with a history of end-stage lung disease, end-stage malignant tumor, G-6-PD deficiency, diabetic ketoacidosis, active kidney stone disease, and severe kidney disease Patients who have already enrolled in another clinical trial Patients with a known history of kidney disease, chronic renal failure, or acute renal failure during hospitalization

Age

From 18 years old

Gender

Both

Phase

2

Groups that have been masked

No information

Sample size

Target sample size: 200

Randomization (investigator's opinion)

Randomized

Randomization description

Simple randomization; randomization unit: individual; randomization tool: using EXCEL software in two groups randomly

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Tabriz University of Medical

Sciences

Street address

Research Vice-Chancellor, Tabriz University of Medical Sciences, Golgasht Street

City

Tabriz

Province

East Azarbaijan

Postal code

5166614766

Approval date

2021-08-30, 1400/06/08

Ethics committee reference number

IR.TBZMED.REC.1400.519

Health conditions studied

1

Description of health condition studied

COVID-19 patients

ICD-10 code

U07.1

ICD-10 code description

COVID-19, virus identified

Primary outcomes

1

Description

The amount of lung involvement in a CT scan

Timepoint

Every 12 hours, Up to 10 days

Method of measurement

According to the radiologist, the appearance of lung involvement and the percentage of lung involvement are measured.

Secondary outcomes

1

Description

Oxygen saturation

Timepoint

Every 12 hours, Up to 10 days

Method of measurement

Observations and clinical examinations

2

Description

Respiratory rate

Timepoint

Every 12 hours, Up to 10 days

Method of measurement

Observations and clinical examinations

3

Description

Duration of hospitalization
Timepoint
Daily since hospitalization time
Method of measurement
Based on patient records

4

Description
Mortality rate
Timepoint
Daily
Method of measurement
Census

Intervention groups

1

Description
Intervention group: Vitamin C is made by Osweh Pharmaceutical Company, will be administered 4 grams by injection every 12 hours for 10 days.
Category
Treatment - Drugs

2

Description
Control group: They will not receive any intervention
Category
N/A

Recruitment centers

1

Recruitment center
Name of recruitment center
Imam Reza Hospital
Full name of responsible person
Moloud Balafar
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Tabriz University of Medical Sciences

Full name of responsible person
Mohammad Samiei
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Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Tabriz University of Medical Sciences
Proportion provided by this source
100
Public or private sector
Public
Domestic or foreign origin
Domestic
Category of foreign source of funding
empty
Country of origin
Type of organization providing the funding
Academic

Person responsible for general inquiries

Contact
Name of organization / entity
Tabriz University of Medical Sciences
Full name of responsible person
Moloud Balafar
Position
Assistant Professor
Latest degree
Specialist
Other areas of specialty/work
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Position

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Other areas of specialty/work

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Undecided - It is not yet known if there will be a plan to make this available

Study Protocol

Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan

Not applicable

Informed Consent Form

Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report

Not applicable

Analytic Code

Not applicable

Data Dictionary

Not applicable